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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,367	01/22/2002	James D. Crapo	2661-22	6992

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EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,367	CRAPO ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *August 18&November 28, 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *11-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *04/25/02;06/13/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 11-28 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper submitted August 18, 2003.

2. Applicant's election without traverse of invention group I, claims 1-10, and compound 10113 as the elected species in Papers submitted August 18, 2003 and November 28, 2003 is acknowledged.

3. The claims have been examined insofar as they read on the elected invention and species.

Double Patenting Rejection

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-20 of copending Application No. 09/880,125, in view of Kobayashi et al. '125 claims a method of protecting cell from oxidant, or treating patient with a pathological condition resulting from oxidant-induced toxicity by using pyridine substituted porphyrin.

6. '125 does not expressly teach for treating cancers, or employment of the particular compound, 10113.

7. However, Kobayashi teaches that human cancer patient usually suffer from oxidative stress. Kobayashi et al. further teaches to employ superoxide dismutase mimetic for treating cancer patient to relieve the oxidative stress.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use the claim method for treating cancer patient.

A person of ordinary skill in the art would have been motivated to use the claim method for treating cancer patient because cancer patients are known to have oxidative stress and superoxide dismutase mimetic are known to be useful for treating cancer patient for relief of such oxidative stress. As to the employment of the particular compound, 10113, it is seen to be a selection from amongst equally suitable material and as such obvious. Ex parte Winters 11 USPQ 2nd 1387 (at 1388) (R is ethyl group in 10113 vs. R is C1-C8 in the claims of '125).

This is a provisional obviousness-type double patenting rejection.

Claim Rejections 35 U.S.C. 103

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claims 1-10 are provisionally rejected under 35 U.S.C. 103(a) as being obvious over copending Application No. 09/880,125 which has a common assigned with the instant application, in view of Kobayashi et al. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e) if published or patented. This provisional rejection under 35 U.S.C. 103(a) is based upon a presumption of future publication or patenting of the conflicting application. '125 claims a method of protecting cell from oxidant, or treating patient with a pathological condition resulting from oxidant-induced toxicity by using pyridine substituted porphyrin.

11. '125 does not expressly teach for treating cancers, or employment of the particular compound, 10113.

12. However, Kobayashi teaches that human cancer patient usually suffer from oxidative stress. Kobayashi et al. further teaches to employ superoxide dismutase mimetic for treating cancer patient to relieve the oxidative stress.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to use the claim method for treating cancer patient.

A person of ordinary skill in the art would have been motivated to use the claim method for treating cancer patient because cancer patients are known to have oxidative stress and superoxide dismutase mimetic are known to be useful for treating cancer patient for relief of such oxidative stress. As to the employment of the particular compound, 10113, it is seen to be a selection from amongst equally suitable material and as such obvious. Ex parte Winters 11 USPQ 2nd 1387 (at 1388) (R is ethyl group in 10113 vs. R is C1-C8 in the claims of '125).

13. This provisional rejection might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by a showing of a date of invention for the instant application prior to the effective U.S. filing date of the copending application under 37 CFR 1.131. For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(l)(1) and § 706.02(l)(2).

14. Claims 1-10 are directed to an invention not patentably distinct from claims 16-20 of commonly assigned application 09/880,125 for reasons discussed above.

The U.S. Patent and Trademark Office normally will not institute interference between applications or a patent and an application of common ownership (see MPEP § 2302).

Commonly assigned application 09/880,125, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

15. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kobayashi et al. in view of Bloodsworth et al.

16. Kobayashi et al. teaches that mimetic of superoxide dismutase are useful for treating human cancer patients. See, particularly, the abstract.

17. Kobayashi et al. do not teach expressly to employ compound 10113 herein as the mimetic of superoxide dismutase.

18. However, Bloodsworth et al. teaches that 10113 is a known superoxide dismutase mimetic. See, particularly the abstract.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ 10113 as the superoxide dismutase mimetic in the method for treating cancer patient as disclosed by Kobayashi et al.
A person of ordinary skill in the art would have been motivated to employ 10113 as the superoxide dismutase mimetic in the method for treating cancer patient as disclosed by Kobayashi et al. because 10113 is a known super oxide dismutase mimetic. The employment of 10113 as superoxide dismutase mimetic is seen to be a selection from amongst equally suitable material and as such obvious. Ex parte Winters 11 USPQ 2nd 1387 (at 1388).

19. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wheelhouse et al. (US 6,087,493, IDS).

20. Wheelhouse teaches a method of treating cancer by using various porphyrin compounds, which have four aromatic substituents. The aromatic substituent may be pyridine with a N-alkyl group. Therefore the porphyrines disclosed by Wheelhouse encompass 10113 herein. Particular example disclosed by Wheelhouse include tetra(N-methyl-4-pyridyl)porphyrine. See, particularly, the abstract, and the claims.

21. Wheelhouse does not teach expressly the employment of 10113.

However, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ 10113 as the porphyrin in the method for treating cancer as disclosed by Wheelhouse et al.

A person of ordinary skill in the art would have been motivated , to employ 10113 as the porphyrin in the method for treating cancer as disclosed by Wheelhouse et al.because 10113 is

with the scope disclosed by Wheelhouse. The employment of 10113 as porphyrin compound herein is seen to be a selection from amongst equally suitable material and as such obvious. Ex parte Winters 11 USPQ 2nd 1387 (at 1388).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (571)272-0632. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

SHENGJUN WANG
PRIMARY EXAMINER

Shengjun Wang

February 16, 2004